

Serial No.: 09/619,899
Group Art Unit: 1616

Remarks

Claims 1-17, 19-48, and 50-53 are pending in this application. Claims 1, 7, 19, 28, 33 and 50 have been amended to more clearly define the invention.

Acknowledgment is made of the Advisory Action mailed January 20, 2004 (Paper No. 200401116) in which certain rejections in the Office Action were withdrawn (priority objection, objections to ASTM standards and texture analyzes model TA.XTii); and in which certain rejections were maintained (objection to the term "sexual dysfunction agent," reference to the increase in weight of the hydrogel, and the objection regarding the term "active agent").

Claim Rejections under 35 U.S.C. §112, Second Paragraph

Claims 1-17, 20-23, 25-43, 45-48, and 50-53 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Office Action states that the phrase "effective dose of a sexual dysfunctional active agent" does not appear to indicate what would constitute a sexual dysfunctional active agent or effective dose thereof.

Applicants respectfully disagree. However, without conceding the correctness of the rejection, Applicants have amended the claims to recite "an effective dose of an erectile dysfunctional active agent." It is submitted that the claims as amended are definite. Reconsideration and withdrawal of the rejection are respectfully requested.

The Office Action further rejected claims 7 and 33 under 35 U.S.C. § 112, second paragraph because the phrase "a hydration rate in 24 hours of 5-20% at 75% humidity at room temperature" renders the claims indefinite as it is uncertain what the percent relates to. The Examiner suggests amending the claims to recite that the increase of the hydrogel is indicated in terms of weight percent.

Applicants have amended claims 7 and 33 according to the Examiner's suggestion. Applicants respectfully submit that one of ordinary skill in the art would understand that the increase in the hydration rate of 5-20% signifies the increase in the weight of the hydrogel. In paragraph 32 of the present Application, the hydration rate is defined "here and in the claims as the speed of absorbing water at 25°C and 75° relative humidity in 24 hours. In Table 1 on page 17, following paragraph 66, the composition of the coating solution in weight percent is set forth

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for several different hydrocolloids. Please note that in the last entry, water, is given in weight percent; thus, one of ordinary skill looking at the definition and looking at Table 1 would conclude that the hydration rate would be in the term of the weight percent of the original film. Since the components of the film are given in weight percent, one would expect that the increase in the amount of water would also be in weight percent based on the original weight of the hydrocolloids.

The Examiner further asserts that claim 28, 50 are indefinite in their recitation of the phrase "an additional active agent" as it is uncertain whether Applicant means an additional "sexual dysfunction active agent" which may be the same or different from the "sexual dysfunction active agent" or any other active agent. Claims 28 and 50 have been amended to indicate that the "addition active agent" is an agent other than the "sexual dysfunction active agent". As such, Applicants respectfully request that this rejection be withdrawn.

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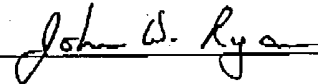
CONCLUSION

As all of the outstanding rejections have been addressed and all of the claims are believed to be in condition for allowance, the Applicants respectfully request a Notice of Allowability. The Examiner is invited to contact the undersigned representative should any further issues arise.

Respectfully submitted,

DECHERT LLP

Date: July 1, 2004



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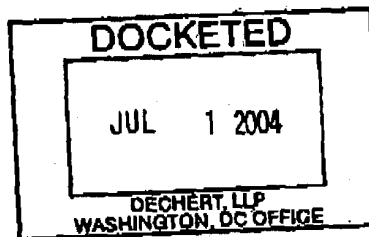
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Please find below and/or attached an Office communication concerning this application or proceeding.





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Paper No.

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 6-2-04 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see *68 Fed. Reg. 38611*, Jun. 30, 2003). In order for the amendment document to be compliant, correction of the following item(s) is required. Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted. 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____
- ☐ 3. Amendments to the drawings: _____
- ☒ 4. Amendments to the claims:
- ☒ A. A complete listing of all of the claims is not present. *Claims 18 and 24 missing*
 - ☐ B. The listing of claims does not include the text of all claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/procnotice/officesflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given **ONE MONTH** from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH** time limit is not extendable.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for an RCE), and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a **TIME PERIOD** of **ONE MONTH** from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

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Rev. 10/03